

**Empire State Stem Cell Board
Funding Committee Meeting Minutes
December 11, 2009**

The Empire State Stem Cell Board Funding Committee held a meeting on Friday, December 11, 2009, at the Department of Health offices, 90 Church Street, New York, New York. Commissioner Richard F. Daines, M.D., presided as Chairperson.

Funding Committee Members Present:

Dr. Richard F. Daines, Chairperson
Mr. Kenneth Adams
Dr. Bradford Berk*
Mr. Robin Elliott
Dr. Gerald Fischbach
*via videoconference

Dr. David Hohn, Vice Chair*
Dr. Bruce Holm*
Dr. Hilda Hutcherson
Dr. Allen Spiegel
Dr. Michael Stocker

Funding Committee Members Absent:

Dr. Richard Dutton

Ms. Madelyn Wils

Ethics Committee Members Present:

Fr. Thomas Berg
Ms. Nancy Neveloff Dubler
Dr. Samuel Gorovitz*
*via videoconference

Dr. Vivian Lee
Dr. Samuel Packer
Mr. Robert Swidler

Department of Health Staff Present:

Ms. Bonnie Brautigam
Dr. Kathy Chou
Ms. Judy Doesschate
Dr. Matthew Kohn

Ms. Beth Roxland
Ms. Lakeria Rucker
Dr. Lawrence Sturman
Ms. Kathy Zdeb

Observers Present:

Ms. Lourdes Bahamonde
Mr. Matthew Bahamonde
Ms. Jean Ellison
Mr. Ed Ellison
Ms. Crystal Mainiero
Mr. David McKeon

Ms. Caroline Marshall
Ms. Katalin Polgar
Ms. Kristin Smith
Ms. Susan Solomon
Ms. Kelly Ryan

Opening Remarks and Introductions

Dr. Daines called the meeting to order and welcomed Board members, staff and the public. He advised members that he recently presented the NYSTEM team with a Commissioner's Recognition Award for their outstanding work. He stated that Teresa Ascienzo, Connie Gardner, Kenneth Peek, Mary Thatcher, Matthew Kohn, Kathy Chou, Marti McHugh, Linda Tripoli, Jerroo Kotval, Katherine Zdeb, Cindy Miner, Fred Genier, Mary Beth Hefner, Lakeria Rucker, Mary Szesnat, Diane Mathis, Claire Pospisil, Jill Taylor and Amy Nickson are all members of the NYSTEM team that work largely behind the scenes serving critical roles to help

make the NYSTEM program a success. He noted that most of these staff members have many other responsibilities and are not funded through the Empire State Stem Cell Trust Fund, but have gone above and beyond their normal duties to make the NYSTEM initiative a success.

Dr. Daines then asked members and staff to introduce themselves.

Approval of Minutes for the October 26, 2009, Funding Committee Meeting

Dr. Daines directed members to the draft minutes for the October 26, 2009, meeting of the Funding Committee in their agenda books and asked for a motion to approve the minutes. Dr. Stocker so moved and Mr. Adams seconded the motion. The motion passed.

Motion to Convene in Executive Session

Dr. Daines advised members and the public that the Committee needed to go into executive session to discuss the evaluations of the applications submitted in response to the Request for Applications (RFA) for Targeted Projects in Human Embryonic Stem Cell Research. He then asked for a motion to move into executive session. Dr. Spiegel so moved. Dr. Fischbach seconded the motion. The motion passed.

Dr. Daines then asked members of the public and non-essential staff to leave the room and advised them that the Committee was expected to reconvene in public in about a half hour.

Executive Session

Dr. Daines noted that some members of the Committee would need to be recused for the discussion of some applications, but that Dr. Sturman would first be providing members with information about the evaluation process and applications for which there were no conflicts of interest. Dr. Sturman and Ms. Brautigam reminded members of the evaluation criteria included in the RFA and provided members with information about the peer review evaluation process. The Committee was then provided with specific information relating to the applications while members who were identified as having a potential conflict of interest left the room during consideration of certain applications.

Motion to Adjourn Executive Session

Dr. Daines then asked for a motion to adjourn the executive session and reconvene in public. Dr. Spiegel so moved and Dr. Hutcherson seconded the motion. The motion passed.

Motion to Reconvene Into Executive Session

Upon reconvening in public, Dr. Hohn advised the Chair that members participating via videoconference from Rochester were unable to hear or participate in parts of the executive session discussion due to technical problems. Dr. Daines clarified that Dr. Hohn would like to reconvene in executive session to be heard on those matters. Dr. Spiegel then moved to go into executive session and Dr. Stocker seconded the motion. The motion passed and the public was asked to leave the room. In executive session, members recapped their discussions and listened to comments from members attending the meeting via videoconference from Rochester.

Motion to Adjourn Executive Session

Dr. Daines then asked for a motion to adjourn executive session and reconvene in public. Dr. Hohn so moved and Dr. Spiegel seconded the motion. The motion passed unanimously.

Recommendations for Approval of Targeted Projects in Human Embryonic Stem Cell Research

Dr. Daines welcomed the public back and advised the Committee that it would be taking up the recommendation of awards for applicants who responded to the RFA for funding of Targeted Projects in Human Embryonic Stem Cell Research. Dr. Daines noted that the applications were reviewed by a panel of independent experts from outside New York State and that summaries of the reviews were discussed by the Funding Committee in executive session.

Ms. Brautigam provided a brief overview of the evaluation criteria and process. Dr. Daines then advised members that they would first act on the recommendation for the award for which no Committee members had declared a conflict of interest and then take up the applications for which members of the Committee had identified a conflict of interest. Dr. Daines then asked Dr. Sturman to provide information on the first application for which there was no conflict of interest. Dr. Sturman provided the following information on the recommended award:

| PI | Sponsoring Institution | Application# | Proposal Title | Recommended Funding |
|--------------|----------------------------------|--------------|--|---------------------|
| Paluh, Janet | Rensselaer Polytechnic Institute | NO9T-011 | Derivation of Xenofree Human Embryonic Stem Cell Lines from Minority Populations | \$992,553 |

Dr. Spiegel then moved to recommend approval of this award in the amount recommended by staff. Dr. Hutcherson seconded the motion. The motion passed.

The Committee then considered the following applications while Dr. Stocker recused himself and left the room:

| PI | Sponsoring Institution | Application # | Proposal Title | Recommended Funding |
|---------------|-------------------------------|---------------|---|---------------------|
| Noggle, Scott | New York Stem Cell Foundation | NO9T-10 | Derivation of Genetically Diseased Human Embryonic Stem Cell Lines | \$990,364 |
| Egli, Deiter | New York Stem Cell Foundation | NO9T-002 | Derivation of Pluripotent Human Stem Cells by Somatic Cell Nuclear Transfer | \$931,586 |

Mr. Elliott moved to recommend approval of the awards in the amounts recommended by staff. Dr. Berk seconded the motion. The motion passed. Dr. Stocker returned to the room.

Discussion and Possible Action on “Accelerating Stem Cell Research through Consortia” Request for Applications

Dr. Sturman then referred Committee members to the RFA entitled *Accelerating Stem Cell Research through Consortia* included in their agenda books. He stated that the RFA was developed based upon the Committee’s feedback on the concept paper provided at the last

meeting and consultation with many researchers. He noted that there seemed to be agreement that the consortia would better serve as a single project rather than a program project or center award. He stated that the purpose is to support science along the developmental pipeline from the mid to end point and towards clinical trials. Dr. Sturman noted that the applicant must present a “compelling explanation of their capability to achieve a significant and measurable advance within the period of the award.” He also stated that the proposal could focus on any disease condition, group of diseases, conditions or organ system and must have a patient-oriented health outcome focus moving towards clinical trials.

Dr. Gorovitz expressed his concern that the stringent language of the RFA might discourage strong applicants and suggested the language be changed from “compelling” to “plausible” and that “capability to achieve” to “capability to contribute.” Dr. Sturman concurred with the change from “compelling” to “plausible,” but expressed concern that the suggested change to “capability to contribute” would open the door to anything. He acknowledged that very few applicants would be able to meet the proposed standards in the RFA, but that he did not want others to unnecessarily spend effort on it. Dr. Sturman then turned the floor over to Dr. Kohn to report on recent staff discussions with scientists regarding these issues.

Dr. Kohn advised members that staff had consulted nine translationally-oriented researchers regarding realistic opportunities for therapeutic development in certain areas and planned to consult with others. One of the nine investigators focused on a drug screening approach, seven focused on cell-based therapies and one investigator was using both approaches. Six investigators were using somatic stem cells and three were using pluripotent stem cells. Two of the investigators reported that they are already conducting clinical trials. Two other investigators indicated they could file an Investigational New Device (IND) application within three or four years. None of the investigators using pluripotent stem cells expressed confidence that they could file an IND application within that period. Several investigators stressed the need for funding to support earlier phase translational studies, including developing protocols for directed differentiation, use of disease specific cells and assays in drug discovery phase. A number of investigators also suggested there is a role for commercial entities, but that many cell therapies would not be commercially profitable and would most likely be performed in hospital and academic settings. Dr. Kohn noted that several researchers encouraged NYSTEM to not emulate the California Institute for Regenerative Medicine (CIRM) disease team proposal because of its narrow focus on achieving an IND or some other artificial goal.

Ms. Dubler applauded the program’s initiative toward translational research but expressed concern about the additional scientific review needed after a proposal is approved. Dr. Fischbach suggested changing the words “to clinical applications” in the RFA to “through clinical applications” to make it clear that the RFA would support research that involves clinical applications. Dr. Berk stated that since a number of investigators are likely to apply for this RFA from within a single academic institution the RFA should expressly limit how many awards an institution may receive to maximize the impact across the entire State.

Dr. Sturman then highlighted several provisions in the draft RFA, including that: 1. the minimum percent effort for the principal investigators would be thirty percent and twenty percent for the co-principal investigator; 2. each consortia would be required to have a full time project manager; 3. each consortia would be required to have a scientific oversight panel that will report to NYSTEM staff about the progress of the consortia and that the contract will be terminated if there is insufficient progress; 4. the RFA proposed up to five awards that would be

capped at \$12.5 million in direct costs over five years for a potential total commitment of \$75 million; and 6. a two-stage review process is established during which potential recipients would need to submit a pre-application and then a full application.

Dr. Spiegel noted that California used four-year terms and questioned whether the RFA should require the principal investigators to have experience working with for-profit or industry organizations. Dr. Stocker noted that some presenters at the consortia planning meeting had suggested the Committee should focus on researchers who have been commercialized, but wondered if it was too early to impose that kind of requirement. Dr. Sturman suggested that the requirement could be softened by indicating that such experience is desirable, as opposed to required. Dr. Hohn suggested that the steering committee or leadership team should include a consultant with for-profit or commercialization experience rather than requiring the principal investigator to have that experience. Ms. Dubler suggested that it might be good to have the oversight leadership team include a person with a background in ethics if the proposal involves clinical trials. Dr. Spiegel noted that any projects involving clinical trials would need to be reviewed by an Institutional Review Board (IRB). Dr. Hohn also noted that applicable regulations require all phase one trials to have a data safety monitoring board that is independent of the investigator.

Members briefly discussed the amount of funding proposed in the draft RFA and agreed that the amounts proposed were appropriate and needed to stimulate interest among researchers. Dr. Sturman thanked members for the feedback and stated that staff would refine the RFA and submit a revised RFA to the Committee for a vote at its next meeting.

Discussion and Possible Action on RFAs for Additional Training Opportunities

Dr. Daines then directed members to the two RFAs for stem cell research training opportunities that were included in the Committee's agenda binders for their consideration. He turned the floor over to Dr. Sturman to highlight significant provisions in those RFAs.

Dr. Sturman explained that the Short Term Faculty Training Opportunities RFA would commit \$1 million for institutions to be able to support faculty members while they pursue stem cell research training at other institutions. He stated that the award would allow institutions to cover up to \$5,000 a month in expenses for faculty members, but that no faculty member would be able to receive more than three months of support. Each institution would be able to provide up to six months of support each year, for three years. He noted that Wadsworth Center staff will not be eligible to participate in this RFA and that the review will be completed internally by program staff.

Dr. Sturman then advised members that the second RFA would enable medical, dental and veterinary school students to pursue research experience at a stem cell laboratory at their home institution or one of their choice for up to a year. He noted that institutions would also be the applicants for this RFA and each award is expected to fund two students over a three-year period, totaling \$1.5 million. In response to a question about why M.D./Ph.D. candidates were excluded from funding, Dr. Sturman noted that the RFA was intended for students who do not have research experience built into their training programs and that M.D./Ph.D. students had the ability to work in a stem cell laboratory for their doctorate.

Dr. Daines asked for a motion to approve the Empire State Dental, Medical and Veterinary Student Training Program RFA. Dr. Stocker so moved and Dr. Spiegel seconded the motion. The motion passed.

Dr. Daines then asked for a motion to approve the Short Term Faculty Training RFA. Dr. Spiegel so moved and Dr. Hohn seconded the motion. The motion passed.

Discussion of Funding Allocation for Pending RFAs

Dr. Daines then turned the floor over to Dr. Sturman to provide the Committee with information on the applications received in response to the Shared Facilities RFA issued in August and the possibility of increasing the funding available for this RFA.

Dr. Sturman advised members that the Committee previously allocated \$15 million to the Shared Facilities RFA and that the number of responses was much higher than expected. He noted that the funds currently allocated would only support three awards. Dr. Sturman suggested that the Committee increase the funds committed for this RFA to \$30 million to provide the Committee with greater flexibility to make awards once these applications are reviewed. Dr. Sturman noted that while this would bring the total amount allocated to shared facilities to more than the amount established in the Board's five year Strategic Plan, facilities needed to be developed earlier in the process to accommodate funded researchers. He also noted that the awards made would extend into the sixth and seventh years of the program. Dr. Sturman stated that he thought the development of the facilities will encourage more stem cell research and make New York researchers more competitive for funding from other sources.

Mr. Elliott expressed concern about how much funding would remain if the allocation for the RFA was increased as recommended and inquired if the decision could be delayed. Ms. Doesschate reminded members that this merely increased the amount available and the Committee's flexibility when they consider their award recommendations, but that when they see the applications they could decide to fund less. In response to a concern expressed regarding the potential for shared facilities not being used for stem cell research, Dr. Sturman advised members that staff does on-site reviews and requires documentation of the uses.

Dr. Daines then asked for a motion to increase the amount of funding to be made available through the Shared Facilities RFA issued in August from \$15 million to \$30 million. Dr. Stocker so moved and Mr. Adams seconded the motion. The motion passed.

Adjourn

Dr. Daines then asked for a motion to adjourn the Funding Committee meeting. Dr. Fischbach so moved. Dr. Hutcherson seconded the motion. The motion passed.

*s/ Judy L. Doesschate, Esq.
Executive Secretary to the
Empire State Stem Cell Board
Approved:*